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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/677,108 | 09/29/2000 | Lynn Joens | M0-4890 | 2035 |

157 7590 12/03/2001

BAYER CORPORATION
PATENT DEPARTMENT
100 BAYER ROAD
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EXAMINER

ZEMAN, ROBERT

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1645

DATE MAILED: 12/03/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/677,108

Applicant(s)

JOENS, LYNN

Examiner

Robert A Zeman

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 1998.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 22 and 26, in part, drawn to whole culture vaccines, classified in class 424, subclass 93.4.
- II. Claims 1-7, 22 and 26, in part, drawn to inactivated culture vaccines, classified in class 424, subclass 93.4.
- III. Claims 1-8, 22 and 26, in part, drawn to modified live formulation vaccines, classified in class 424, subclass 93.4.
- IV. Claims 1-7, 22 and 26, in part, drawn to vaccines from *Lawsonia intracellularis* extracts, classified in class 424, subclass 278.1.
- V. Claims 1-7, 9-10, 22 and 26, in part, drawn to subunit vaccines, classified in class 424, subclass 204.1.
- VI. Claims 1-7, 9-10, 22 and 26, in part, drawn to recombinant vaccines, classified in class 424, subclass 204.1.
- VII. Claims 1-7, 22 and 26, in part, drawn to naked DNA vaccines, classified in class 514, subclass 44.
- VIII. Claim 11, drawn to monoclonal antibodies, classified in class 530, subclass 388.4.
- IX. Claim 12, drawn to method of growing *Lawsonia intracellularis*, classified in class 435, subclass 325.
- X. Claim 13, drawn to method of producing inactivated culture vaccines, classified in class 435, subclass 325.
- XI. Claim 14, drawn to method of producing a modified live vaccine, classified in class 935, subclass 65.

Art Unit: 1645

- XII. Claims 15-16, drawn to methods of producing subunit vaccines, classified in class 435, subclass 455.
- XIII. Claims 17-18, drawn to methods of producing recombinant subunit vaccines utilizing genomic library screens, classified in class 935, subclass 35.
- XIV. Claims 19-20, drawn to methods of producing recombinant subunit vaccines utilizing target immunogen sequencing, classified in class 935, subclass 35.
- XV. Claim 21, drawn to method of producing recombinant subunit vaccines utilizing monoclonal antibodies, classified in class 935, subclass 35.
- XVI. Claim 23, drawn to method of diagnosing proliferative ileitis, classified in class 435, subclass 7.32.
- XVII. Claims 24-25, drawn to methods of determining antigenic mass, classified in class 435, subclass 7.32 or class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VIII are separate and distinct from each other, as they each comprise differing biochemical and immunological entities having differing properties and uses. Each invention is drawn a unique vaccine composition or monoclonal antibody

Inventions IX-XVII are separate and distinct from each other as they are drawn to differing methods having different steps and leading to differing results.

Inventions I and IX are related as product and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the cells of Invention I can be obtained from infected animals.

Art Unit: 1645

Inventions II and X are related as product and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the cells of Invention II can be obtained from infected animals

Inventions III and XI are related as product and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the cells of Invention III can be obtained from infected animals

Inventions V and XII are related as product and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the cells of Invention V can be obtained from infected animals.

Inventions VI is related as product and process of making. to Inventions XIII-XV. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the subunit vaccines of Invention V can be obtained using a multitude of techniques including: PCR, genomic library screening and antibody mapping.


Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Art Unit: 1645

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Lynette Smith, can be reached at (703)308-3909.



DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman
11/27/01